

**Notice of Allowability****Application No.**

10/081,817

**Applicant(s)**

POLYAK ET AL.

**Examiner**

Gary B. Nickol Ph.D.

**Art Unit**

1642

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 06-04-04.
2. ☒ The allowed claim(s) is/are 23,24,35 and 38-46.
3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |   |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)  | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)           |
| 2. <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                                 | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                   |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material          | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance             |
|   | 9. <input type="checkbox"/> Other _____   |

  
**GARY NICKOL**  
**PRIMARY EXAMINER**

Gary B. Nickol Ph.D.  
Primary Examiner  
Art Unit: 1642

### EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Stuart Macphail, Ph.D., J.D. on June 4, 2004.

The application has been amended as follows:

23. (Currently amended) A method of diagnosis, the method comprising:
- (a) providing a test cell;
  - (b) determining, in the test cell, the degree of methylation of one or more C residues in a nucleotide sequence in a genomic segment, the genomic segment ~~consisting~~ of comprising (i) a CpG island in the HIN-1 5' promoter region (SEQ ID NO:19) and (ii) the first twelve nucleotides of SEQ ID NO:3, wherein the one or more C residues are C residues in CpG sequences; and
  - (c) comparing the degree of methylation of the one or more C residues to the degree of methylation of corresponding one or more C residues in a corresponding genomic segment in a control cell, wherein a higher degree of methylation of the one or more C residues in the test cell than in the control cell is an indication that the test cell is a cancer cell.
24. (Original) The method of claim 23, wherein the test cell is a breast cell.
- 25.-34. (Cancelled)
35. (Previously presented) The method of claim 23, wherein the test cell is selected from the group consisting of a lung cell, a prostate cell, a pancreatic cell, a gastrointestinal cell, and a skin cell.
36. (Cancelled)
37. (Cancelled)
38. (Previously presented) The method of claim 23, wherein the nucleotide sequence comprises nucleotide 1 to nucleotide 252 of SEQ ID NO:19.

39. (Previously presented) The method of claim 23, wherein the nucleotide sequence consists of nucleotide 1 to nucleotide 252 of SEQ ID NO:19.

40. (Previously presented) The method of claim 23, wherein the nucleotide sequence comprises nucleotide 229 to nucleotide 551 of SEQ ID NO:19 and nucleotide 1 to nucleotide 12 of SEQ ID NO:3.

41. (Previously presented) The method of claim 23, wherein the nucleotide sequence consists of nucleotide 229 to nucleotide 551 of SEQ ID NO:19 and nucleotide 1 to nucleotide 12 of SEQ ID NO:3.

42. (Previously presented) The method of claim 23, wherein the nucleotide sequence comprises SEQ ID NO:19 and nucleotide 1 to nucleotide 12 of SEQ ID NO:3.

43. (Previously presented) The method of claim 23, wherein the nucleotide sequence consists of SEQ ID NO:19 and nucleotide 1 to nucleotide 12 of SEQ ID NO:3.

44. (Previously presented) The method of claim 23, wherein the test cell is a human cell.

45. (Previously presented) The method of claim 23, wherein the degree of methylation is determined by sequencing of bisulfite-treated DNA comprising the nucleotide sequence.

46. (Previously presented) The method of claim 23, wherein the degree of methylation is determined by a methylation-specific polymerase chain reaction (MCP) assay.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 571-272-0835. The examiner can normally be reached on M-Th, 8:30-5:30; alternate Fri., 8:30-4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary B. Nickol Ph.D.  
Primary Examiner  
Art Unit 1642

June 11, 2004



**GARY NICKOL**  
**PRIMARY EXAMINER**